DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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November 14, 2014

Excelsior Medical Corporation
Mr. John Linfante
Vice President RA/QA
1933 Heck Avenue
Neptune, NJ 07753

Re: K133446
Trade/Device Name: Heparin Lock Flush, USP
Regulation Number: 21 CFR 880.5200
Regulation Name: Heparin, Vascular Access Flush
Regulatory Class: II
Product Code: NZW
Dated: October 16, 2014
Received: October 16, 2014

Dear Mr. Linfante

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133446

Device Name

Heparin Lock Flush, USP

Indications for Use *(Describe)*

Flushing of IV catheters and IV tubing only. Solution is intended for maintenance of patency of intravenous injection devices. Prior to and after administration of intermittent medication, entirely flush the intravenous injection device (catheter and or tubing) with Heparin Lock Solution, USP. Use in accordance with any warnings or precautions appropriate to medication being administered. This device is not to be used for anticoagulant therapy.

Heparin Lock Flush, USP is supplied as:

- 3 USP Units per 3 mL (1 USP unit per mL); 3 mL volume in a 10 mL syringe
- 6 USP Units per 3 mL (2 USP unit per mL); 3 mL volume in a 10 mL syringe
- 30 USP Units per 3 mL (10 USP unit per mL); 3 mL volume in a 10 mL syringe
- 50 USP Units per 5 mL (10 USP unit per mL); 5 mL volume in a 10 mL syringe
- 300 USP Units per 3 mL (100 USP unit per mL); 3 mL volume in a 10 mL syringe
- 500 USP Units per 5 mL (100 USP unit per mL); 5 mL volume in a 10 mL syringe

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Manufacturer Name:	Excelsior Medical Corporation
Address:	1933 Heck Avenue Neptune, NJ 07753
Contact Name:	John Linfante
Title:	Vice President RA/QA
Phone Number:	732-643-6088
Fax Number:	732-776-7600
Date Prepared:	October 16, 2014

Device Proprietary Name:	Heparin Lock Flush, USP
Device Common or Usual Name:	Heparin Lock Flush, USP
Classification Name:	Heparin, Vascular Access Flush
Classification Code:	NZW
Regulation Number:	21 CFR Part 880.5200
Device Classification	II

Predicate Devices:

Substantial equivalence is claimed to the following devices as related to intended use, design, and material characteristics:

- Syrex Pre-Filled Syringe, 10 U/mL & 100 U/mL, Excelsior Medical Corporation, K023740
- Syrex Heparin Lock Flush Syringe, 1 U/mL & 2 U/mL, Excelsior Medical Corporation, K061497

Description of the Device

Excelsior Medical's Heparin Lock Flush, USP devices are provided as terminally sterilized, single-use, pre-filled, pre-packaged products. The products contain a solution of heparin sodium, USP and 0.9% sodium chloride, USP. The solution is delivered through the luer lock of a venous access device to maintain catheter patency (lock catheters) between treatments. Typically, the venous access device is flushed with normal saline before and after the administration of intermittent medication therapy, blood sampling, total parenteral nutrition, or hemodialysis.

Heparin Lock Flush, USP is available as follows:

- Heparin Lock Flush, USP, 3 USP Units per 3 mL (1 USP unit per mL); 3 mL volume in a 10 mL syringe
- Heparin Lock Flush, USP, 6 USP Units per 3 mL (2 USP unit per mL); 3 mL volume in a 10 mL syringe

- Heparin Lock Flush, USP, 30 USP Units per 3 mL (10 USP unit per mL); 3 mL volume in a 10 mL syringe
- Heparin Lock Flush, USP, 50 USP Units per 5 mL (10 USP unit per mL); 5 mL volume in a 10 mL syringe
- Heparin Lock Flush, USP, 300 USP Units per 3 mL (100 USP unit per mL); 3 mL volume in a 10 mL syringe
- Heparin Lock Flush, USP, 500 USP Units per 5 mL (100 USP unit per mL); 5 mL volume in a 10 mL syringe

The product is intended for use with commercially available valves and catheters fitted with a standard mating luer lock or luer taper.

Intended Use/Indications for Use

Flushing of IV catheters and IV tubing only. Solution is intended for maintenance of patency of intravenous injection devices. Prior to and after administration of intermittent medication, entirely flush the intravenous injection device (catheter and or tubing) with Heparin Lock Flush, USP. Use in accordance with any warnings or precautions appropriate to medication being administered. This device is not to be used for anti-coagulant therapy.

Technological Characteristics

The heparin lock/flush syringes subject to this filing have been previously cleared by FDA under K023740 and K061497. A comparison of the products is provided in the table below.

510(k) Number		**K061497**	**K023740**
Device Name	Heparin Lock Flush, USP	Syrex Heparin Lock Flush Syringes	Syrex Pre-Filled Syringe
Manufacturer	Excelsior Medical Corporation		
Intended Use	Flushing of IV catheters and IV tubing only. Solution is intended for maintenance of patency of intravenous injection devices. Prior to and after administration of intermittent medication, entirely flush the intravenous injection device (catheter and or	Excelsior Medical Heparin Lock Flush Solutions (1 Unit/mL and 2 Units/mL) are indicated for use in maintaining patency of vascular access devices designed for intermittent or infusion therapy. Prior to and after administration of intermittent medication, entirely	Flushing of IV catheters and IV tubing only. Prior to and after administration of intermittent medication, entirely flush the catheter and/or tubing with Heparin Lock Flush Solution, either USP 10 Units/mL, or USP 100 Units/mL. Use in accordance with

	tubing) with Heparin Lock Flush, USP. Use in accordance with any warning or precautions appropriate to medication being administered. This device is not to be used for anti-coagulant therapy.	flush the vascular access device with Heparin Lock Flush Solution, USP. Use in accordance with any warning or precautions appropriate to medication being administered. This device is not to be used for anti-coagulant therapy	any warning or precautions appropriate to medication being administered. This device is not to be used for anti-coagulant therapy. Protect from freezing and avoid excessive heat. Store at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F).
Solution	Heparin Lock Flush Solution, USP (0.9% Sodium Chloride Injection, USP)	Heparin Lock Flush Solution, USP (0.9% Sodium Chloride Injection, USP)	Heparin Lock Flush Solution, USP (0.9% Sodium Chloride Injection, USP)
Concentrations	1 U/mL 2 U/mL 10 U/mL 100 U/mL	1 U/mL 2 U/mL N/A N/A	N/A N/A 10 U/mL 100 U/mL
Single Use Device	Yes	Yes	Yes
Sterility	Terminally sterilized via steam; SAL 10^{-6}	Terminally sterilized via steam; SAL 10^{-6}	Terminally sterilized via steam; SAL 10^{-6}
Barrel Material	Polypropylene and silicone lubricant	Polypropylene and silicone lubricant	Polypropylene
Plunger Rod Material	Medical grade polypropylene	Medical grade polypropylene	Medical grade polypropylene
Piston	Synthetic isoprene rubber	Synthetic isoprene rubber	Synthetic isoprene rubber
Tip Cap	Medical grade polypropylene and TPE plus colorant	Medical grade polypropylene and TPE plus colorant	Medical grade polypropylene and TPE plus colorant
Tip Cap Colorants	1 U/mL - Green 2 U/mL - Lavender 10 U/mL - Blue 100 U/mL - Yellow	1 U/mL – Green 2 U/mL - Lavender	10 U/mL - Blue 100 U/mL - Yellow
Packaging	Tamper evident over-wrap	Tamper evident over-wrap	Tamper evident over-wrap

As seen above there are no significant differences between the subject and predicate devices. The purpose of this submission is to add alternate suppliers of the heparin sodium (USP) raw material for all of Excelsior Medical's heparin products.

Non-Clinical Testing

The following studies have been performed or are being relied upon to support the safety and effectiveness of the product:

- Raw material qualification
- Biocompatibility (ISO 10993-1)
- Stability Studies
- Sterilization validation (ISO 17665-1 and -2)
- Extractables/Leachables
- Testing of final product to Heparin Lock Flush Solution USP Monograph

Conclusion

As noted above, the only change to the Heparin Lock Flush, USP products as cleared in K023749 and K061497 is the source of heparin. This change is supported by the studies cited above, and results of the testing show that there are no new questions of safety and effectiveness. Therefore, it is concluded that the product is as safe and as effective for use, and is substantially equivalent to the identified predicate devices.